



#17
Decl.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Ashley J. Birkett)	
)	Attorney Docket:
Serial No.:	09/931,325)	ICC-103.1 US
)	83502
Filed:	August 15, 2001)	
)	
For:	Malaria Immunogen)	Group Art Unit 1648
	and Vaccine)	
)	
Examiner:	Zachariah Lucas)	

DECLARATION OF DR. ASHLEY BIRKETT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

DR. ASHLEY BIRKETT Declares;

1. That the is the Ashley Birkett who is the named inventor of the above-identified patent application;
2. That he is the Vice President of Research of Apovia, Inc. the assignee of the above-identified application;
3. That he has read and is familiar with the Office Action mailed February 10, 2003;
4. That in regard to the Action's assertions in Paragraph 11 as to the reported failures noted in the Table at pages 100-102 of the specification for peptide epitopes

from a Plasmodium species, he notes that only one peptide was from a circumsporozoite (CS) protein;

5. That the failed peptide construct was from *P. vivax* and was referred to as the V2.Pv-T1A construct;

6. That although there was one failure using a sequence from the *P. vivax* CS protein, he and those working under his direction and control in the Apovia research laboratories in San Diego, California, were successful in preparing chimer particles that incorporated an epitope from the *P. vivax* CS protein, as well as particles that contained a *P. vivax* CS protein epitope and a *P. vivax* or *P. falciparum* T cell epitope;

7. That the Table below provides data that illustrate those particle preparations as well as the single failure;

8. That the data in that Table reflect all of the studies carried out to date involving attempted syntheses of HBc chimeric immunogens containing a peptide epitope from *P. vivax*;

Table

<i>p. vivax</i> Types Covered (I, II, III)	<i>p. vivax</i> B cell Epitope Sequence	T cell Epitope Sequence	C-terminal Cys Stabilization	Yield (mg/0.5L)
I	PAGDRAD <u>G</u> QPA <u>G</u> DRAAGQPA G	-	No	-
I	DRAAGQPA <u>G</u> DRAD <u>G</u> QPA <u>G</u>	-	No	37.1
I	DRAAGQPA <u>G</u> DRAD <u>G</u> QPA <u>G</u>	-	Yes	39.0
T	-	EYLDKVRATVGTEWTPCSVT	Yes	28.1
IIA	ANGAGN <u>Q</u> PGANGAGD <u>Q</u> PG	-	No	18.7
IIB	ANGADN <u>Q</u> PGANGADD <u>Q</u> PG	-	No	23.2
IIA, IIB	ANGAGN <u>Q</u> PGANGAGD <u>Q</u> PGAN GADN <u>Q</u> PGANGADD <u>Q</u> PG	-	No	23.5
III	APGANQEGGAAAPGANQEGG AA	-	No	69.6
I, *T	DRAAGQPA <u>G</u> DRAD <u>G</u> QPA <u>G</u>	EYLNKIQNSLSTEWSPCSVT	Yes	>21.0
I, T	DRAAGQPA <u>G</u> DRAD <u>G</u> QPA <u>G</u>	EYLDKVRATVGTEWTPCSVT	Yes	49.5
IIA, T	ANGAGN <u>Q</u> PGANGAGD <u>Q</u> PG	EYLDKVRATVGTEWTPCSVT	Yes	37.3
IIB, T	ANGADN <u>Q</u> PGANGADD <u>Q</u> PG	EYLDKVRATVGTEWTPCSVT	Yes	45.0
IIA, IIB, T	ANGAGN <u>Q</u> PGANGAGD <u>Q</u> PGAN GADN <u>Q</u> PGANGADD <u>Q</u> PG	EYLDKVRATVGTEWTPCSVT	Yes	>20.4
III, T	APGANQEGGAAAPGANQEGG AA	EYLDKVRATVGTEWTPCSVT	Yes	45.8

Key:

Underlined amino acids represent those known to be associated with substitution;

T*, *P. falciparum* CS T cell epitope;

T, *P. vivax* CS T cell epitope ;

Yields preceded by '>' reflect loss of material during purification due to equipment errors.

9. That the above data expand upon the data provided in Example 9 of the application that begins on page 110 of the specification;

10. That the data of Example 10 Table 12 (pages 114-115) show that the *P. vivax* chimer construct identified as V2.PV-TIB on page 111 exhibited a titer of about 160,000 as compared to the titer of 1200 exhibited by the *P. falciparum* CS-2 construct of Schödel et al. that is noted in that table and elsewhere;

11. That all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful, false statements may jeopardize the validity of the above-identified application or any patent issuing thereon.

8th JULY 2003

Date



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CERTIFICATE OF MAILING

I hereby certify that this a Declaration, along with a Reply and Amendment, a Petition for Two-Month Extension of Time and it's fee, Form 1449 and Art, are being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on July 10, 2003.

By



Edward P. Gamson